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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,234	09/10/2003	Guenter Mueller	DEAV2002/0065 US NP	3093
5487	7590	06/12/2006	EXAMINER	
ROSS J. OEHLER SANOFI-AVENTSI U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			RAO, MANJUNATH N	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 06/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,234

Applicant(s)

MUELLER ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 28-36, 41 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21, 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 12-15, 17, 18, 20, 22, 24, 25, 39, 40, 43 and 44 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 16, 19, 23, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-44 are currently pending and are present for examination. Claims 1-6, 12-27, 37-40, 43-44 are now under consideration. Claims 7-11, 28-36, 41-42 remain withdrawn from consideration, being drawn to non-elected invention.

Election/Restrictions

Applicant's election of Group I, claims 1-6, 12-27, 37-40, 43-44 in the reply filed on 4-6-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Objections

Claims 1, 3, 4, 16, 18, 25 are all objected to because of the following informalities: These claims recite an abbreviation "GLUT4V85M" without providing the expansion for the abbreviation. Applicant is urged to provide the full expansion for the above abbreviation. Appropriate correction is required.

Claims 12, 14, 17, 21, 39, 40 are all objected to because of the following informalities: These claims recite an abbreviation "erg4" or "Fgy1" without providing the expansion for the

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abbreviation. Applicant is urged to provide the full expansion for the above abbreviations.

Appropriate correction is required.

Claim 12 is objected to because of the following informality: Claim 12 recites the phrase “transporters are no function, and..” which has improper grammar. Appropriate correction is required.

Duplicate claims (Warning)

Applicant is advised that should claim 13 be found allowable, claim 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 17 and claims 13-15 and 43 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12 and 17 recite the phrase “A yeast cell from *Saccharomyces cerevisiae*”. The metes and bounds of the above phrase are not clear to the Examiner. It is not clear as to what applicants mean by “from *Saccharomyces cerevisiae*”. The questions that arise from the above phrase is regarding the

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structure and function of the cell “from *Saccharomyces cerevisiae*”, whether it is the same as the starting cell or whether it becomes a different cell, whether the cell has the same properties as that of the parent cell? Examiner suggests, applicants amend the phrase to the one they have recited in other claims such as “An isolated *Saccharomyces cerevisiae* yeast cell” or the like.

Claim 39 and claims 40 and 44 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 depends from claim 39, which does not make scientific sense. Examiner urges applicants to change the claim dependency in order to overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15, 24, 43-44 are rejected because the invention appears to employ novel host cells transformed with novel vectors. Since the host cells and vectors are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed host cells and plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The specification does not disclose a repeatable process to obtain the vectors and host cells and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made

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in accordance with 37 CFR 1.801-1.809. In order for the claims to be enabled, applicants must show that either the host cells and the plasmids can be made by publicly available materials or that the host cell comprising the plasmid as such has been deposited in such a way that it is freely available to the public. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids and the host cells that are transformed using said plasmids.

The deposits can be made in a recognized Biological Deposit Center. It appears that applicants have made the deposit under the terms of the Budapest Treaty. In order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific plasmid/strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent. Such an affidavit or a Declaration would satisfy the deposit requirement made herein.

Claims 1, 4, 6, 12-15, 22, 25, 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide with SEQ ID NO:1 encoding a Glucose transport protein (GLUT4) comprising the amino acid sequence SEQ ID NO:2, vectors comprising said polynucleotide and host cells transformed with said vectors, does not reasonably provide enablement for any or all polynucleotide encoding any or all GLUT4 polypeptides, including variants and mutants of the same, along with vectors comprising said polynucleotide and host cells transformed with said vectors. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 4, 6, 12-15, 22, 25, 43 are so broad as to encompass any or all polynucleotide encoding any or all GLUT4 polypeptides, including variants and mutants of the same, along with vectors comprising said polynucleotide and host cells transformed with said vectors. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a given polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in said encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the polynucleotide with SEQ ID NO:1 and the encoded amino acid sequence of a single polypeptide with SEQ ID NO:2 having GLUT4 activity. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides. The

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specification is limited to teaching the use of SEQ ID NO: 1 and the encoded polypeptide SEQ ID NO:2 as a GLUT4 but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any or all polynucleotides encoding GLUT4 polypeptides because the specification does not establish: (A) regions of the encoded protein structure which may be modified without affecting its glucose transport activity; (B) the general tolerance of glucose transport proteins to modification and extent of such tolerance; (C) a rational and

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predictable scheme for modifying any amino acid residue on said protein with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides with an enormous number of modifications of SEQ ID NOS:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1, 4, 6, 12-15, 22, 25, 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NO:1 or DNA having the limitations of encoding a protein having glucose transport activity. The specification does not contain any disclosure of the structure of all DNA sequences that are encompassed in the above claims. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of having many different structures. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses

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only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 18, 20, are rejected under 35 U.S.C. 102(b) as being anticipated by Fukumoto et al. (JBC, 1989, Vol. 264(14):7776-7779 and Gen Bank Acc No. M20747, 1995). This rejection is based upon the public availability of a printed publication. Claims 1, 4-6, 18, 20, of the instant application are drawn to a polynucleotide encoding a glucose transport protein (which applicants label as GLUT4V85M, Examiner has not given any patentable weight to this label), wherein said polynucleotide is linked to a promoter, wherein said polynucleotide hybridizes to SEQ ID NO:1 under stringent conditions, and a vector comprising said polynucleotide in which it is

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operationally linked to a promoter. Fukumoto et al. disclose a polynucleotide which is 99.9% identical to SEQ ID NO:1, encoding a glucose transport protein (which applicants label as GLUT4V85M, Examiner has not given any patentable weight to this label), wherein said polynucleotide is linked to a promoter, wherein said polynucleotide, because of the high sequence similarity hybridizes to SEQ ID NO:1 under stringent conditions, and a vector comprising said polynucleotide in which it is operationally linked to a promoter. Thus Fukumoto et al. anticipate claims 1, 4-6, 18, 20, of this application as written.

Claims 1, 4-6, 18, 20, are rejected under 35 U.S.C. 102(e) as being anticipated by Ward et al. (US Pub 20040101848A1, filed on 11-23-2002) or Venter et al. (US Pub 2005147987, filed on 7-5-2005 with US priority date 9-8-2000). This rejection is based upon the public availability of a printed publication. Claims 1, 4-6, 18, 20, of the instant application are drawn to a polynucleotide encoding a glucose transport protein (which applicants label as GLUT4V85M, Examiner has not given any patentable weight to this label), wherein said polynucleotide is linked to a promoter, wherein said polynucleotide hybridizes to SEQ ID NO:1 under stringent conditions, and a vector comprising said polynucleotide in which it is operationally linked to a promoter. Ward et al. or Venter et al. disclose a polynucleotide which is 99.9% identical to SEQ ID NO:1, encoding a glucose transport protein (which applicants label as GLUT4V85M, Examiner has not given any patentable weight to this label), wherein said polynucleotide is linked to a promoter, wherein said polynucleotide, because of the high sequence similarity hybridizes to SEQ ID NO:1 under stringent conditions, and a vector comprising said polynucleotide in which it is operationally linked to a promoter (see enclosed sequence

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alignment). Thus Ward et al. or Venter et al. anticipate claims 1, 4-6, 18, 20, of this application as written.

Allowable Subject Matter

Claims 21, 26, 27 are allowable.

Claims 2-3, 12, 14, 16, 19, 23, 37-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath', with a stylized flourish at the end.

Manjunath N. Rao, Ph.D.
Primary Examiner
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June 8, 2006

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